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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/722,070

11/24/2000

Brian S. Kelleher

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30328 7590 04/12/2007  
JONATHAN SPANGLER  
NU VASIVE, INC.  
4545 TOWNE CENTRE COURT  
SAN DIEGO, CA 92121

EXAMINER

DOERRLER, WILLIAM CHARLES

ART UNIT

PAPER NUMBER

3744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/722,070	<b>Applicant(s)</b> KELLEHER ET AL.	
	<b>Examiner</b> William C. Doerfler	<b>Art Unit</b> 3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 22-26 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 22-26 and 30-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15,16,22-26 and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raymond et al '153 in view of Feler et al.

Raymond et al '153 discloses applicants' basic inventive concept, a method for determining the location of a nerve by electrically signaling the nerve and detecting the response using EMG (column 6 line 12 of '153) and determining when the signal is below a threshold signifying close proximity to the nerve (see column 3 lines 21-55) and using a visual or audible alarm to signal the proximity to the nerve, thus signaling the intensity of the signal,(column 7 lines 3-23), substantially as claimed with the exception

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of using the process on a spinal nerve. While this is seen as a matter of design choice since all the nerves in a body function on the same principle, Feler et al nevertheless shows electrically determining the location of spinal nerves to be known in the art. It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Feler et al to modify the detection system of Raymond et al '153 by enabling the use for spinal nerves to enable safe operations in the vicinity of the spinal cord. In regard to claim 32, iteration to determine the proper position of the nerve is seen as well within the scope of the ordinary practitioner as a confirmation of the placement of the nerve to reduce the chances of an accidental an irreparable severing of the nerve. The first paragraph of column 7 discusses the signaling of the intensity which detects the nerve. Raymond et al discussing the increasing of the intensity of the signal until a nerve is located, beginning in line 44 of column 3.

### ***Response to Arguments***

Applicant's arguments filed 3-12-2007 have been fully considered but they are not persuasive. While the defining characteristics of the spine make the claim more definite, they are not seen to add any allowable structure to the claim. The additions to the preamble of the claim recite structure that is present in every normal human spine. While the addition does make it clear which direction the probe is entering from, entering from any angle is seen as obvious in light of the applied references. Applicant has not supplied any reasoning why an approach from the lateral direction is somehow better, or that the method of the proposed combination will not function from a lateral direction.

On page 7 of the 3-12-2007 response, applicant states that increasing signals from a right and a left probe is not shown by the references. It is unclear where the two probe approach has been claimed.

The examiner agrees that a lateral approach is not expressly stated in any of the applied references. None of the references state a preferred approach direction. This implies that the nerves may be approached from any angle, and the devices will function properly. The examiner still fails to see why stating that approaching the spine is approaching a nerve is a "gross misunderstanding". It is unclear how one can approach the spine without approaching a nerve, as the spinal chord is essentially a nerve. Approaching the spine without approaching a nerve appears the same as approaching a house without approaching a room in the center of the house. The references teach a method of detecting a nerve, when approaching that nerve with a probe. This is seen to include any major nerve in the human body. As the spinal chord is a major nerve in the human body, the references are seen to be applicable. As the references are seen to include approaching any nerve from any angle, this is seen to include approaching the spinal column from a lateral direction. While the spine includes more than nerve tissue, it is unclear how one can approach the spine and not be approaching the major nerve of the body. Regarding the increasing of the signal until a nerve is located. It is noted that Raymond et al '153 in lines 44-51 discuss the increasing of the signal until a response is detected, at which time the signal is decreased.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William C. Doerrler whose telephone number is (571) 272-4807. The examiner can normally be reached on Monday-Friday 6:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571) 272-4834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William C Doerrler  
Primary Examiner  
Art Unit 3744

WCD